K013264

NOV 2 9 2001

Appendix A (Summary of Safety And Effectiveness)

Submitter:
John Gagliardi, President **(contact person)**
MidWest Process Innovation, LLC
7736 Woodside Court
Maineville, OH 45039
513-573-0085 (Telephone and fax) **or**
513-573-0519 (Telephone and fax)
JGAGL777@One.Net

Trade Name: Micro Stamping Corporation (MSC) Ligating Clip

Common Name: Ligating Clip

Classification Name: Implantable Clip (21 CFR, Part 878.4300)

Summary of Safety and Effectiveness:
The MSC Ligating Clip is substantially equivalent in function and intended use to the Edward Weck and Company Hemoclip Ligating Clip (see example of labeling in Appendix E of products presently on the market) and the Ethicon Ligaclip.

Specifically:
the MSC Ligating Clip is exactly similar in functional design, performs the same functions and has the same intended use as these presently distributed devices mentioned above.
The packaging methods and packaging materials are exactly the same, respectively.

The MSC Ligating Clip is indicated for use as to connect internal tissues to aid in healing. This device is for prescription use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2001

Micro Stamping Corporation
MidWest Process Innovation, LLC
C/o John Gagliardi
President
7736 Woodside Court
Maineville, Ohio 45039

Re: K013264
Trade/Device Name: MSC Ligating Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: September 25, 2001
Received: October 1, 2001

Dear Mr. Gagliardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MP

Celia M. Witten, Ph.D., M.D.
Director
Divison of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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MICRO STAMPING CORP.
the stamp of quality

Attachment II

Indications for Use

Re: K013264

Device Name: MSC Ligating Clip

Indications for Use:
A clip like device intended to connect internal tissues to aid in healing. These clips are designed for occlusion of blood vessels and nerves, according to surgeon judgement.

(please do not write below this line – continue on another page if needed)

Prescription Use__X__ or Over-the-Counter Use_____
(Per 21 CFR, Part 801.109)

Optional Format 1-2-96

Susan Walker
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013264